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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,808	05/12/2005	Nicholas John Heightman	2847-1-001US	6600

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EXAMINER

VAKILI, ZOHREH

ART UNIT	PAPER NUMBER
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1614

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11/01/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/501,808	Applicant(s) HEIGHTMAN ET AL.	
	Examiner Zohreh Vakili	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/04/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-8 are presented for examination.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST

PARAGRAPH:

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

claims 5 and 6 are directed to encompass agents, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these agents, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed*. (See page 1117). The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See Vas-Cath at page 1116).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed agents, derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as anticipated by Ratain et al. (US Pub. No. 20020016293 A1).

Ratain et al. disclose new compositions and formulations, including pharmacologically acceptable formulations, that comprise one or more first flavopiridols in combination with one or more second agents. Such compositions may include the first flavopiridol drug or drugs in combination with Oltipraz, **clofibrate**, ciprofibrate, fenofibrate, bezafibrate, **gemfibrozol**; and will preferably include flavopiridol in

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combination with dexamethasone, rifampin or clofibrate (see page 6, paragraph 59).

The compositions may also include one or more first flavopiridol drugs in combination with a cyclosporine or staurosporine, particularly, reserpine, dipyridamole, and **ivermectin** (see page 6, paragraph 60). For oral administration, the active compounds may be administered, for example, with an inert diluent or with an assimilable edible carrier, or they may be enclosed in hard or soft shell gelatin capsule, or compressed into tablets, or incorporated directly with the food of the diet. The active compounds may be incorporated with excipients and used in the form of ingestible tablets, capsules, suspensions, syrups, **wafers**, and the like. Such compositions and preparations should contain at least 0.1% of active compound. The percentage of the compositions and preparations may, of course, be varied and may conveniently be between about 2 to about 60% of the weight of the unit. The amount of active compounds in such therapeutically useful compositions is such that a suitable dosage will be obtained (page 10, paragraph 110). Clofibrate is propanoic acid, 2-(4-chlorophenoxy)-2-methyl-,ethyl ester; Atromid-S and is available from Ayers (see page 11, paragraph 121). Suitable doses for use in adults are contemplated to be similar to those doses used to achieve an antihyperlipidemic effect, namely 500 mg 3 times a day for persons weighing less than 120 lb, 4 times a day for those weighing 120 to 180 lb, and 5 times a day for those over 180 lb, or to achieve an antidiuretic effect, namely 6 to 8 g/day in 2 to 4 divided doses. **Clofibrate** is available in 500 mg capsules (see page 11, paragraph 124). Administration of a single dose of **gemfibrozil** (600 mg) results in a plasma concentration of about 15 Ug/ml after 2 hours and 5 Ug/ml after 9 hours. **Gemfibrozil**

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(LOPID) is available as 300-mg capsules and 600-mg tablets. The usual recommended dosage (for adults only) is 600 mg twice daily, taken 30 minutes before the morning and evening meals (seepage 11, paragraph 128).

Thus, Ratain et al. disclose all limitations of and anticipate claims 1-7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ratain et al.

(US Pub. No. 20020016293 A1) and in view of Pflaumer et al. (US Patent No. 5095008).

Ratain et al. disclose new compositions and formulations, including pharmacologically acceptable formulations, that comprise one or more first flavopiridols in combination with one or more second agents. Such compositions may include the first flavopiridol drug or drugs in combination with Oltipraz, **clofibrate**, ciprofibrate, fenofibrate, bezafibrate, **gemfibrozol**; and will preferably include flavopiridol in combination with dexamethasone, rifampin or clofibrate (see page 6, paragraph 59). The compositions may also include one or more first flavopiridol drugs in combination with a cyclosporine or staurosporine, particularly, reserpine, dipyridamole, and **ivermectin** (see page 6, paragraph 60). For oral administration, the active compounds may be administered, for example, with an inert diluent or with an assimilable edible carrier, or they may be enclosed in hard or soft shell gelatin capsule, or compressed into tablets, or incorporated directly with the food of the diet. The active compounds may be incorporated with excipients and used in the form of ingestible tablets, capsules, suspensions, syrups, **wafers**, and the like. Such compositions and preparations should contain at least 0.1% of active compound. The percentage of the compositions and preparations may, of course, be varied and may conveniently be between about 2 to about 60% of the weight of the unit. The amount of active compounds in such therapeutically useful compositions is such that a suitable dosage will be obtained (page 10, paragraph 110). Clofibrate is propanoic acid, 2-(4-chlorophenoxy)-2-methyl-,ethyl ester; Atromid-S and is available from Ayers (see page 11, paragraph 121). Suitable

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doses for use in adults are contemplated to be similar to those doses used to achieve an antihyperlipidemic effect, namely 500 mg 3 times a day for persons weighing less than 120 lb, 4 times a day for those weighing 120 to 180 lb, and 5 times a day for those over 180 lb, or to achieve an antidiuretic effect, namely 6 to 8 g/day in 2 to 4 divided doses. **Clofibrate** is available in 500 mg capsules (see page 11, paragraph 124).

Administration of a single dose of **gemfibrozil** (600 mg) results in a plasma concentration of about 15 Ug/ml after 2 hours and 5 Ug/ml after 9 hours. **Gemfibrozil** (LOPID) is available as 300-mg capsules and 600-mg tablets. The usual recommended dosage (for adults only) is 600 mg twice daily, taken 30 minutes before the morning and evening meals (see page 11, paragraph 128).

Pflaumer et al. teach the object of the present invention is to provide a method for reducing blood **cholesterol** in a patient in need of such treatment, comprising the administration to the patient of said psyllium-containing or said psyllium- and polyol polyester-containing cookie (see col. 4, lines 1-5). Cookies or **biscuits** might provide a useful way to introduce psyllium into the diet. Psyllium has an undesirable taste and texture (see col. 3, lines 55-58). It would be most desirable to make a palatable psyllium-containing cookie in which the psyllium does not substantially hydrate during the mixing, forming, or baking process, and does not substantially hydrate in the mouth upon eating (see col., lines 59-63). Flavor additives like cereals may also be used, such as bran or oatmeal. From 0% to about 30% of the cookie dough can be such additives (see col. 11, lines 36-42).

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It would have been obvious to one of ordinary skill in the art to use the teachings of Ratain et al. to formulate a sandwich biscuit for the administration of a medicinal substance taken with the teachings of Pflaumer et al. to produce an oatmeal biscuit containing a cholesterol lowering medicament.

One would have been motivated to create such formulation because Ratain et al. teach the administration of a medicinal substance comprising a sandwich biscuit. Pflaumer et al. disclose cookies made of oatmeal incorporated medicine for reducing blood cholesterol levels. Therefore, one of ordinary skill in the art would have been motivated to use the teachings of the above mentioned references to develop a formulation for the administration of a medicinal substance.

Finally, one would have a reasonable expectation of success given that Ratain et al. and Pflaumer et al. provide a detailed blueprint for making a layered biscuits wherein the cream filling comprises the medicament, and the steps of which are routine to one of ordinary skill in the art.

Thus in the absence of evidence to the contrary, the invention of claims 1-8 would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner

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October 17, 2007


ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER